

AMENDMENTS TO THE CLAIMS

Claims 1-78 (cancelled).

79. (new) A method of enhancing the biological activity of a LH-RH peptide analogue which comprises orally administering to a patient in need thereof a pharmaceutical composition comprising a therapeutically effective amount of a peptide analogue in combination with α -cyclodextrin and excipients suitable for the gastrointestinal delivery of the peptide analogue, wherein the α -cyclodextrin enhances the biological activity of the LH-RH peptide analogue when orally administered,

wherein said peptide analogue has the formula (SEQ ID N°1):

A1-A2-A3-A4-A5-A6-A7-A8-Pro-Z (A)

in which :

- A1 is pGlu, DAla or AcDNal;
- A2 is His or D-pClPhe;
- A3 is Trp, DPal or DAla;
- A4 is Ser;
- A5 is Tyr or NicLys;
- A6 is Gly, (S)-spiolactam-Pro, DAla, DLeu, DPhe, DTrp, DNpg, DNal, DNicLys, DCit, DHCit, DAsn, DHArg, DSer(OBu^t) or DHis which is unsubstituted or substituted on the imidazole ring by a benzyl group;
- A7 is Leu, Ada or Npg, where said amino acid is unsubstituted or N-alpha-substituted by a (C₁-C₄)alkyl group;
- A8 is Arg or IprLys;
- Z is GlyNH₂, D-AlaNH₂, azaGlyNH₂ or a group -NHR₂ where R₂ is a (C₁-C₄)alkyl;

and wherein the α -cyclodextrin derivative is selected from the group consisting of methylated α -cyclodextrin, hexakis(2, 3, 6-tri-O-methyl)- α -cyclodextrin, carboxymethylated α -cyclodextrin and phosphated α -cyclodextrin.

80. (new) The method according to claim 79 in which in formula (A):

- A1 is pGlu;
- A2 is His;
- A3 is Trp;
- A5 is Tyr;
- A6 is Gly, (S)-spirolactam-Pro, DAla, DLeu, DPhe, DTrp or DSer(OBu^t);
- A7 is Leu or Npg;
- A8 is Arg;
- Z is GlyNH₂, azaGlyNH₂, or a group -NHR₂ where R₂ is ethyl.

81. (new) The method according to claim 79 in which in formula (A):

- A1 is DAla or AcDNal;
- A2 is DpClPhe;
- A3 is DAla or DPal;
- A6 is DNicLys, DCit, or DAsn;
- Z is D-AlaNH₂.

82. (new) The method according to claim 80 wherein the peptide analogue is selected from the group consisting of leuprorelin, [Npg⁷]-leuprorelin, triptorelin, [Npg⁷]-triptorelin, goserelin, [Npg⁷]-goserelin, buserelin and [Npg⁷]-buserelin.

83. (new) The method according to claim 81 wherein the peptide analogue is selected from the group consisting of antide, [Npg⁷]-antide, cetorelix, [Npg⁷]-cetorelix, abarelix and [Npg⁷]- abarelix.

84. (new) The method according to claim 79 wherein the α -cyclodextrin derivative is hexakis(2, 3, 6-tri-O-methyl)- α -cyclodextrin.

85. (new) The method according to claim 79 wherein the pharmaceutical composition is intended for the treatment of infertility, hypogonadic or hypergonadic states.

86. (new) The method according to claim 79 wherein the pharmaceutical composition is a contraceptive agent.

87. (new) The method according to claim 79 wherein the pharmaceutical composition is intended for the treatment or prevention of prostate cancer or benign prostatic hypertrophy.

88. (new) The method according to claim 79 wherein the pharmaceutical composition is intended for the treatment or prevention of breast cancer.

89. (new) The method according to claim 79 wherein the pharmaceutical composition is intended for the treatment or prevention of sex hormone-related benign or malignant tumors.

90. (new) The method according to claim 79 wherein the pharmaceutical composition is intended for the treatment or

prevention of sex hormone-independent but LH-RH sensitive benign or malignant tumors.

91. (new) The method according to claim 79 wherein the pharmaceutical composition is intended for the treatment or prevention of benign or malignant lymphoproliferative disorders.

92. (new) A pharmaceutical composition for the gastrointestinal delivery by oral administration of an LH-RH peptide analogue, said composition comprising a therapeutically effective amount of a peptide analogue in combination with α -cyclodextrin and excipients suitable for the gastrointestinal delivery of the peptide analogue, wherein the α -cyclodextrin enhances the biological activity of the LH-RH peptide analogue when orally administered, said LH-RH peptide analogue having the formula (SEQ ID N°1):

A1-A2-A3-A4-A5-A6-A7-A8-Pro-Z (A)

in which :

- A1 is pGlu, DAla or AcDNal;
- A2 is His or D-pClPhe;
- A3 is Trp, DPal or DAla;
- A4 is Ser;
- A5 is Tyr or NicLys;
- A6 is Gly, (S)-spirolactam-Pro, DAla, DLeu, DPhe, DTrp, DNpg, DNal, DNicLys, DCit, DHCit, DAsn, DHArg, DSer(OBu^t) or DHis which is unsubstituted or substituted on the imidazole ring by a benzyl group;
- A7 is Leu, Ada or Npg, where said amino is unsubstituted or N-alpha-substituted by a (C₁-C₄)alkyl group;

- A8 is Arg or IprLys;
- Z is GlyNH₂, D-AlaNH₂, azaGlyNH₂ or a group -NHR₂ where R₂ is a (C₁-C₄)alkyl;

and wherein the α -cyclodextrin derivative is selected from the group consisting of methylated α -cyclodextrin, hexakis(2, 3, 6-tri-O-methyl)- α -cyclodextrin, carboxymethylated α -cyclodextrin and phosphated α -cyclodextrin.

93. (new) The pharmaceutical composition according to claim 92 in which in formula (A):

- A1 is pGlu;
- A2 is His;
- A3 is Trp;
- A5 is Tyr;
- A6 is Gly, (S)-spirolactam-Pro, DAla, DLeu, DPhe, DTrp or DSer(Obu^t);
- A7 is Leu or Npg;
- A8 is Arg;
- Z is GlyNH₂, azaGlyNH₂, or a group -NHR₂ where R₂ is ethyl.

94. (new) The pharmaceutical composition according to claim 92 in which in formula (A):

- A1 is DAla or AcDNal;
- A2 is DpClPhe;
- A3 is DAla or DPal;
- A6 is DNicLys, DCit or DAsn;
- Z is D-AlaNH₂.

95. (new) The pharmaceutical composition according to claim 93 wherein the peptide analogue is selected from the

group consisting of leuprorelin, [Npg⁷]-leuprorelin, triptorelin, [Npg⁷]-triptorelin, goserelin, [Npg⁷]-goserelin, buserelin and [Npg⁷]-buserelin.

96. (new) The pharmaceutical composition according to claim 94 wherein the peptide analogue is selected from the group consisting of antide, [Npg⁷]-antide, cetrorelix, [Npg⁷]-cetrorelix, abarelix and [Npg⁷]- abarelix.

97. (new) The pharmaceutical composition according to claim 92 wherein the α -cyclodextrin derivative is hexakis(2, 3, 6-tri-O-methyl)- α -cyclodextrin.

98. (new) The pharmaceutical composition according to claim 92 which further consists of a protease inhibitor and/or an absorption enhancer.